DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Minneapolis District Office
Central Region
212 Third Avenue South
Minneapolis, MN 55401
Telephone: (612) 334-4100
FAX: (612) 334-4134

October 30, 2003

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 04 – 03

Kenneth L. Collier, DVM
Co-owner
Friendship Valley, LLC
E8698 Reinke Road
Clintonville, Wisconsin 54929

Dear Dr. Collier:

On August 20 and 21, 2003, investigators from the Food and Drug Administration (FDA) conducted an investigation into an illegal tissue residue in a dairy cow sold for slaughter as human food by Friendship Valley, LLC of Clintonville, Wisconsin. The investigation revealed serious deviations from the regulations for Extralabel Drug Use in Animals, Title 21, Code of Federal Regulations (C.F.R.), Part 530. These deviations caused an animal drug to be used in a manner that was unsafe under Section 512(a) of the Federal Food, Drug and Cosmetic Act (the Act) and adulterated within the meaning of Section 501(a)(5) of the Act.

On or about February 18, 2003, Friendship Valley, LLC offered a dairy cow (back tag number 35GD8467) for slaughter as human food to [redacted]. U.S. Department of Agriculture (USDA) analysis of tissue samples collected from this cow identified the presence of sulfadimethoxine at 0.32 ppm in the liver and 0.34 ppm in muscle tissue. A tolerance of 0.1 ppm has been established for residues of sulfadimethoxine in uncooked edible tissues of cattle, 21 C.F.R. § 556.640 (copy enclosed).

The extralabel use of approved veterinary or human drugs is permitted if it complies with Sections 512(a)(4) and 512(a)(5) of the Act and 21 C.F.R. Part 530. Our investigation found that you failed to comply with 21 C.F.R. Part 530 in that

- You failed to establish a substantially extended withdrawal period, supported by appropriate scientific information, before marketing of milk or meat prior to prescribing or dispensing an approved animal drug (sulfadimethoxine) for an extralabel use in a food animal. This is required by 21 C.F.R. § 530.20(a)(2)(ii).

- The extralabel use of sulfadimethoxine caused an illegal drug residue. 21 C.F.R. § 530.11(d) prohibits any extralabel use that results in a residue above an established tolerance.

Because you failed to comply with the requirements of 21 C.F.R. Part 530, Friendship Valley, LLC used new animal drugs in an unapproved manner without meeting the requirements for extralabel use set forth in Section 512(a)(4)(A) and 21 C.F.R. Part 530, thereby rendering the drugs unsafe under Section 512 of the Act and adulterated under Section 501(a)(5) of the Act.

It is not necessary for you to personally ship an adulterated drug in interstate commerce to be responsible for a violation of the Act. The fact that you caused the adulteration of a drug that was sold in interstate commerce is sufficient to hold you responsible for a violation of the Act.

The above is not intended to be an all-inclusive list of violations. As a licensed veterinarian, you are responsible for complying with the requirements of the Act, including the extralabel use regulations promulgated under the Act. You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction.

We have enclosed a copy of 21 C.F.R. Part 530 for your reference. We strongly suggest that you review 21 C.F.R. Part 530 and become familiar with all of its requirements so that you can prevent future violations of the Act.

Our investigation also found that your records contain discrepancies regarding the reason for treatment, dosage forms used, and drug dosages for the animal with the sulfadimethoxine residue. You must maintain complete and accurate drug treatment records as part of your overall system to assure that medicated animals have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues.

You should notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be

completed. Also include copies of any available documentation demonstrating that your corrections have been made.

Your reply should be directed to Compliance Officer Timothy G. Philips at the address indicated on the letterhead.

Sincerely,

W. Charles Becoat
Director
Minneapolis District

TGP/ccl

Enclosure: 21 C.F.R. Part 530
21 C.F.R. § 556.640

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